AUG 15 2007

510(k) Summary of Safety and Effectiveness for the
Scorpio® NRG® Knee System

Proprietary Name:	Scorpio® NRG® Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	888.3560 – Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II
Device Product Code:	JWH - prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
For Information contact:	Patricia Setti-LaPerch Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5938 Fax: (201) 831-4938 E-Mail: Patricia.LaPerch@stryker.com
Date Summary Prepared:	July 19, 2007

Device Description

The Scorpio® NRG® Knee System comprises a series of femoral and tibial insert components. The subject Scorpio® NRG® X3® inserts are available in cruciate retaining (CR) and posterior stabilized (PS) designs and are used for the replacement of the bearing/articulating surfaces of the proximal tibia. The modification to the subject devices is the sequentially crosslinked and annealed X3® UHMWPE material process.

Intended Use:

The Scorpio® NRG® Knee System is a sterile, single-use device intended for total knee arthroplasty.

Indications

The Scorpio® NRG® Knee System components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Revision of previous unsuccessful knee replacement or other procedure;

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint
- Absent or non-functioning posterior cruciate ligament

These components are single use only and are intended for implantation with bone cement.

Substantial Equivalence:

The subject Scorpio NRG X3 inserts are a modification to the Scorpio NRG System cleared in K042343 [Scorpio NRG Knee System (Cruciate Retaining Components)] and K030978 (Scorpio NRG Knee System Posterior Stabilized). The determination of the substantial equivalence for the Scorpio NRG X3 inserts is based on this line extension's identical intended use and indications for use and similar design to the previously cleared Scorpio NRG Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Howmedica Osteonics Corp.
% Ms. Patricia Setti-LaPerch
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K071991
Trade/Device Name: Scorpio® NRG® Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: July 19, 2007
Received: July 20, 2007

Dear Ms. Setti-LaPerch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bruehmp
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071991

Device Name: Scorpio® NRG® Knee System

Indications

The Scorpio® NRG® Knee System components are for use in total knee arthroplasty as a result of:

- Painful, disabling joint disease of the knee resulting from degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
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- Absent or non-functioning posterior cruciate ligament

These components are single use only and are intended for implantation with bone cement.

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071991